REMARKS

The Office Action of December 4, 2007 presents the examination of claims 1-9, 13, 14, 28 and 31-33. Claims 1 and 31 are amended herein.

Support for the time following glucose loading now recited in claims 1 and 31 is found in the specification at least at page 10, lines 1-3.

Clarity

Claims 31-33 are rejected under 35 USC § 112, second paragraph for lack of antecedent basis for the term "the urine" in claim 31. The definite article is deleted in claim 31, thus obviating this rejection.

Enablement

Claims 1-9, 13, 14 28 and 31-33 are rejected under 35 USC § 112, first paragraph, for alleged lack of enablement. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

In particular, the Examiner asserts that no time period is specified after the glucose loading during which the sample is to be taken. Claims 1 and 31 now recite such a time period, thus obviating such ground for the instant rejection.

The Examiner also asserts that the specification does not describe how to measure creatinine, though the claims recite the amount of myo-inositol relative to the amount of creatinine. Applicants submit that the specification need not describe that which is well-known in the art at the time the application is filed (*see, e.g. Hybritech, Inc. v. Monoclonal Antibodies, Inc.* 231 USPQ 81 (Fed. Cir. 1986)), and measurement of creatinine was such a well-known technique. The description clearly states at the bottom of page 24 that creatinine was measured by using a commercially available kit "Creatinine-HA Test Wako (Wako Pure

Chemical Industries, Inc.)" Exhibit 1, attached, is an instruction sheet for this commercially available creatinine assay.

Finally, the Examiner asserts that the claims refer to "characteristic values" that are never explained or explicitly defined in the method. However, a "characteristic value" is defined as the normal value found in a sample of patients exhibiting normal glucose tolerance. See, page 8, lines 5-6 of the specification, and also disclosure at the bottom of pages 1 and 3 (describing a "normal" subject) and Table 3 and Examples 1 and 5 disclosing experiments to determine normal values and the data obtained. The Examiner also asserts that the claims refer to a value that is the same as or higher than a characteristic value of 0 to 20 μg myo-inositol per mg creatinine and argues that there is no upper limit to the value providing the diagnosis. Applicants submit that no upper limit must be recited, since the diagnosis is obtained upon exceeding a threshold value, and this is well-described in the specification.

The instant rejection should be withdrawn for all of the above reasons.

Conclusion

Applicants submit that the present application well-describes and claims patentable subject matter. The favorable actions of withdrawal of the standing rejections and allowance of the pending claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Reg. No. 36,623 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: April 4, 2008

Respectfully submitted,

#47,604

By_____
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Enclosures: Exhibit 1
Declaration Regarding Translation